

DEC 10 2003

510(k) Summary of Safety and Effectiveness
Smith & Nephew Locking Bone Plate System

k033669
page 1 of 1

Submitted By: Smith & Nephew, Inc., Orthopaedic Division
1450 Brooks Road, Memphis, TN 38116

Date: November 20, 2003

Contact Person: David Henley, Senior Clin/Reg Affairs Specialist
Tel: (901) 399-6487 Fax: (901) 398-5146

Proprietary Name: Smith & Nephew Locking Bone Plate System

Common Name: Bone Plates and Bone Screws

Classification Name and Reference: 21 CFR 888.3030, single/multiple component
metallic bone fixation appliances and accessories -
Class II
21 CFR 888.3040, smooth or threaded metallic bone
fixation fastener - Class II

Device Product Code and Panel Code: HRS and HWC / Orthopedics / 87

Device Description:

The Smith & Nephew Locking Bone Plate System is a modification of the Smith & Nephew Bone Plate System cleared under K993106. Like the predicate devices listed below, components include various sizes of contoured and straight, locking bone plates, locking bone screws, and compression screws made from stainless steel. Implantable locking plates/screws incorporate a screw-to-plate locking feature which forms a locked, fixed angle construct to aid in holding fracture reduction.

Intended Use:

The Smith & Nephew Locking Bone Plate System is used for adult and pediatric patients as indicated for pelvic, small, and long bone fracture fixation. Indications for use include fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones (particularly in osteopenic bone); treatment of the calcaneal; hip arthrodesis, and provisional hole fixation.

Technological Characteristics:

Components from the Smith & Nephew Locking Bone Plate System are similar to legally marketed devices listed below in that they share similar indications for use, are manufactured from similar materials and incorporate similar technological characteristics.

Substantial Equivalence Information:

When compared to the predicate devices listed below, substantial equivalence is based on similarities in design features, overall indications for use, and material composition.

- Smith & Nephew Bone Plate System – K993106
- Synthes Small Fragment Locking Compression Plate (LCP) – K000684
- Synthes Locking Calcaneal Plate – K991407
- Synthes LCP for the Distal Femur – K000066
- Synthes LCP for the Proximal Tibial – K011978



DEC 10 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David Henley
Senior Clinical/ Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K033669

Trade/Device Name: Smith & Nephew Locking Bone Plate System
Regulation Number: 21 CFR 888.3030, 21 CFR 888.3040
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HRS, HWC
Dated: November 20, 2003
Received: November 21, 2003

Dear Mr. Henley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

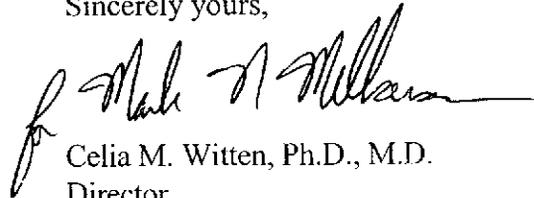
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. David Henley

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement
Smith & Nephew Locking Bone Plate System

510(k) Number (if known): K033669

Device Name: Smith & Nephew Locking Bone Plate System

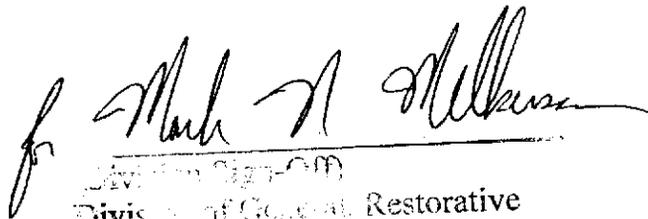
Indications for Use:

The Smith & Nephew Locking Bone Plate System is used for adult and pediatric patients as indicated for pelvic, small, and long bone fracture fixation. Indications for use include fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones (particularly in osteopenic bone); treatment of the calcaneal; hip arthrodesis, and provisional hole fixation.

Components in the Smith & Nephew Locking Bone Plate System are for single use only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Division Chief-ODM
Division of General Restorative
and Neurological Devices

510(k) Number

K033669

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____
(Optional Format 1-2-96)